ToxCO®

User manual

CE 2797

Helping to determine levels of CO poisoning.

Definitions

WARNING: indicates a potentially hazardous situation, which, if not avoided, may result minor or moderate injury.

CAUTION: indicates a potentially hazardous situation, which, if not avoided, may result in damage to the device.

NOTE: used to call attention to notable information that should be followed during use.

Important Information/Reminders

NOTE: Only technical data and no patient data is collected by Bedfont®.

WARNING: Please read the manual before use.

WARNING: Never use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the electrochemical sensor inside.

WARNING: Under no circumstances should the instrument be immersed or splashed with liquid.

WARNING: Breath tests must only be carried out with Bedfont® accessories. Failure to do so may cause incorrect readings.

WARNING: The mouthpieces are single patient use only and can be used for a maximum of 3 tests. Further re-use could cause incorrect readings and could increase the risk of cross infection. The mouthpiece should be disposed of after use, in accordance with local waste disposal guidance.

WARNING: Patients should exhale for the duration of time indicated by the device during a breath test. Failure to do so may cause incorrect readings.

WARNING: To ensure a breath sample is taken at the correct flow rate, the device must be held upright at all times during a breath test.

WARNING: Do not block the exhaust ports on the device at any time. Blocking the exhaust ports may cause erroneous readings.

CAUTION: Ensure the device is used within the stated operating temperature and humidity ranges. Operating temperature is 0-50°C. Operating humidity is 15-90% RH (non-condensing).

CAUTION: Portable and mobile RF communications equipment can affect the ToxCO® device.

NOTE: When selecting an accessory for the ToxCO® device, please be advised that an accessory not recommended by Bedfont® may result in loss of performance and damage to the ToxCO® device. The product warranty does not cover product failure or damage resulting from use with non-approved accessories.

NOTE: See Bedfont's infection control and maintenance guidelines for further information on infection control.

NOTE: Please do not attempt to modify the equipment in any way or use accessories not specified by the manufacturer. Any attempt to do so, will invalidate the warranty and may compromise the safety of the device.

NOTE: Bedfont® will make available on request service training to appropriately qualified personnel.

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Introduction

Carbon monoxide is a toxic, odourless, colourless, tasteless gas[1]. It is formed from incomplete combustion of organic material at high temperatures with an insufficient oxygen supply[3]. When inhaled, CO competes successfully with oxygen in the bloodstream to form carboxyhaemoglobin (COHb). This starves the body tissues of the oxygen vital for repair, regeneration and general living.

CO can remain in the bloodstream for up to 24 hours, depending on a range of factors including physical activity, gender and inhalation intensity[9]. The half-life is about 5 hours with no treatment (normal environmental conditions), 1.5 hours if 100% oxygen is given and 0.58 hours if hyperbaric oxygenation at 100% oxygen is given[8].

Breath carbon monoxide is measured in parts per million (ppm) and blood carboxyhaemoglobin in percentages (%COHb). The 2 measurements are compatible and convertible, CO relating to lung/breath and COHb to blood gas as demonstrated by the conversion graph in the appendix on page 147. The device displays %COHb, but can also display in ppm if selected in the settings. CO ppm readings indicate the levels of poisonous inhaled CO, while the %COHb reading shows the percentage of vital oxygen that has been replaced in the bloodstream[7].

Clinical research has demonstrated that 'the concentration of carbon monoxide in end-expired air after breath holding correlates closely with carboxyhaemoglobin concentration'[12].

Operation of the ToxCO® is straightforward; a D-piece™ sampling system and face mask sampling modes allow the user to test a patient independent of their consciousness, whilst the ambient sampling mode helps to safeguard the user by alerting them if they are entering areas with high levels of CO.

A colour touchscreen ensures ease of operation, and all readings are automatically logged. Additionally, all breath test readings can be tagged with a place or patient ID for quick reference at a later date and time.

Compliance

The ToxCO® device is CE marked according to the Medical Device Directive 93/42/EEC.

Please refer to the ‘Safety Information’ section of this manual for more information on the compliance of the ToxCO® device.

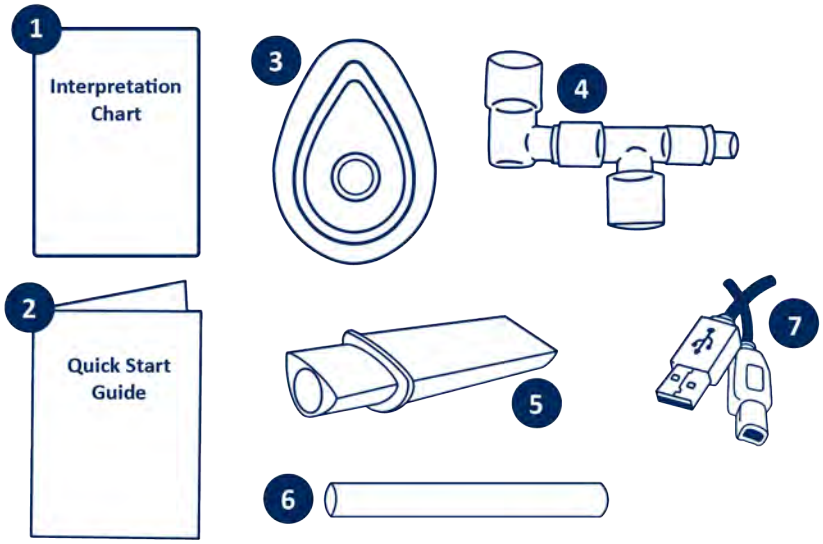
Intended Use

The ToxCO® breath Carbon Monoxide device and accessories are used by healthcare professionals to determine levels of Carbon Monoxide (CO) poisoning.

Contraindications

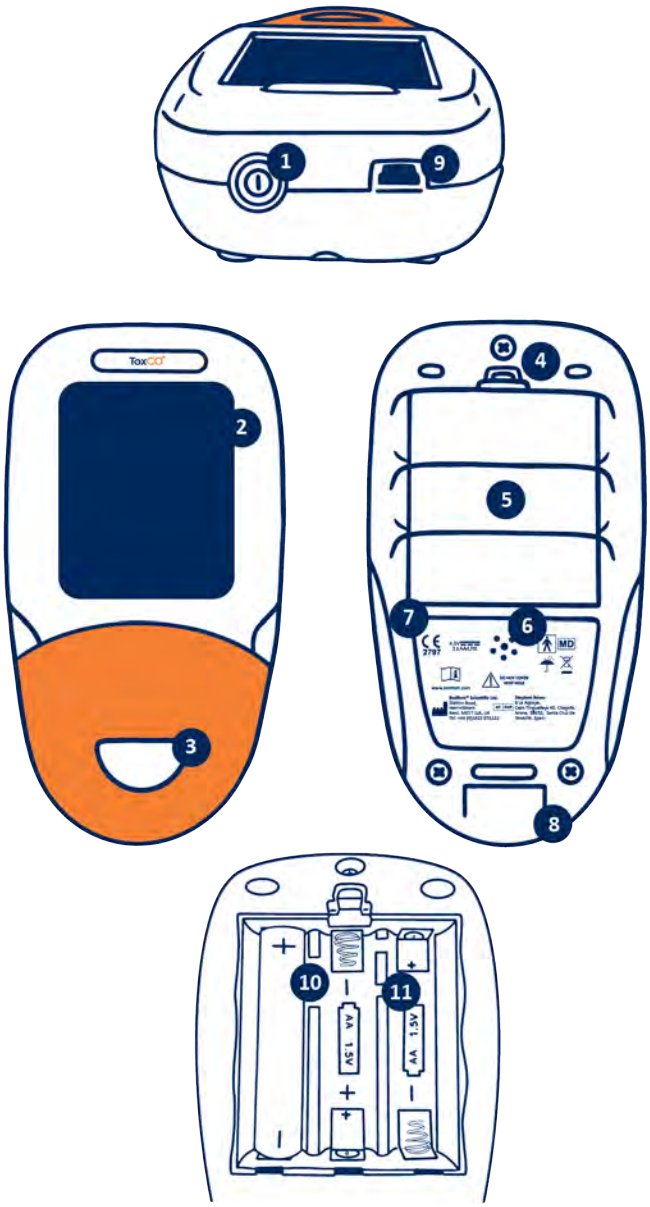
There are no known contraindications.

Parts and Accessories



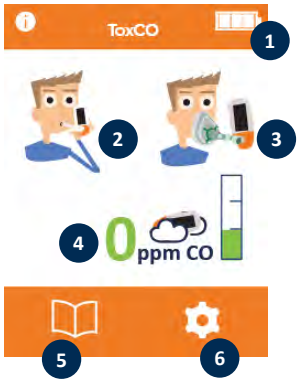
1. Interpretation Chart
2. Quick Start Guide
3. Face mask
4. Face mask sampling system
5. D-piece™
6. Single patient use SteriBreath™ Eco mouthpiece
7. USB connector

Instrument Layout



1. Power button
2. Display
3. D-piece™ aperture
4. Battery compartment clip
5. Battery compartment
6. Vent hole
7. Manufacturer label
8. Exhaust port for breath sample
9. USB port
10. Reset button
11. Programming switch

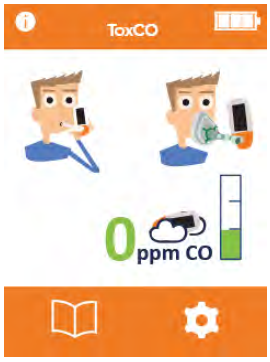
User Interface



Home Screen

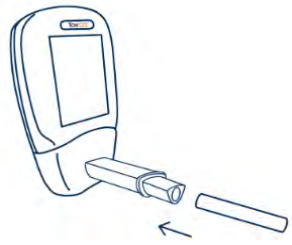
1. Battery status
2. Breath test
3. Face mask breath test
4. Ambient test
5. Patient profiles
6. Settings

Taking a breath test

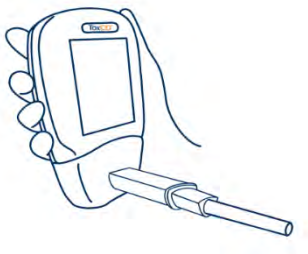


Turn on the device by pressing the power button once.

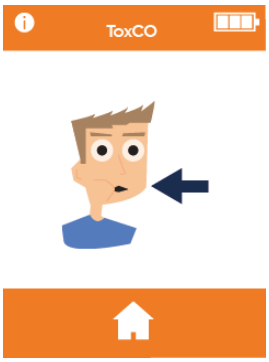
Press the breath test icon on screen.



Attach a breath sampling D-piece™ and SteriBreath™ Eco mouthpiece.



Inhale and hold breath for the pre-set 15 second countdown as shown on screen. If unable to hold breath for full 15 seconds, the timer can be adjusted in the settings.



Press the home button at any time to cancel the breath test.

A beep will sound during the last 3 seconds of the countdown.

Blow slowly into mouthpiece, aiming to empty lungs completely.

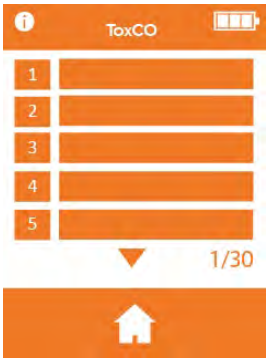
The %COHb and equivalent ppm levels will rise and hold on-screen.

When the test is finished, the breath test, home and patient profile icons will appear at the bottom of the screen.

The alarm may be muted by pressing the mute button.

To repeat breath test, press the breath test icon and repeat steps.

To return to the home screen, press the home icon.



Results save automatically in the breath test log however, there is the option to tag a result with a place, patient's name or ID. To tag a result, press the patient profile icon and enter the place/ID/patient's name. Press the save button.

Remove the D-piece™ between tests to purge sensor with fresh air.

The unit will also power off after 8 hours of inactivity to save power. The display dims after 5 minutes and turns off after 15 minutes.

Taking a face mask test

The appropriate size face mask should be placed over the nose and mouth of the patient, care being taken to avoid leaks around the mask cushion. The patient can then breathe normally, whilst being encouraged to exhale as much as possible.

To use the face mask, select the appropriate mask and attach to the face mask sampling system. This is then connected to the device in place of the mouthpiece.

The face mask sampling procedure does not require a 15 second breath hold to be performed before the test can begin.

NOTE: *If the patient has shallow breathing the measurements from this sampling method may be low and therefore should only be interpreted as an indication of Carboxyhemoglobin levels.*

NOTE: *The face mask testing protocol has been developed for use on patients, with a respiration rate of between 12-20 breaths per minute. If face mask testing is used outside of these specifications, this may result in decreased accuracy of readings.*

Attach a new face mask sampling system in conjunction with the D-piece™. Turn on the device by pressing the power button once.

Press the face mask breath test option.

Inhale and exhale into the face mask, the device will take the reading in real-time.

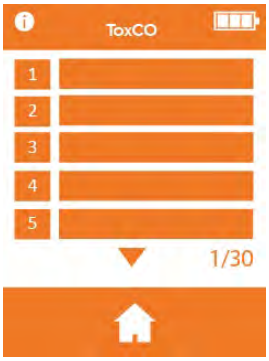
Sampling will last 60 seconds as the %COHb/ppm levels rise and then hold at the peak level. The result will be shown onscreen.

When the test is finished, the face mask breath test, music, home and save icons will appear at the bottom of the screen.

The alarm may be muted by pressing the mute button.

To repeat breath test, press the face mask breath test icon and repeat steps.

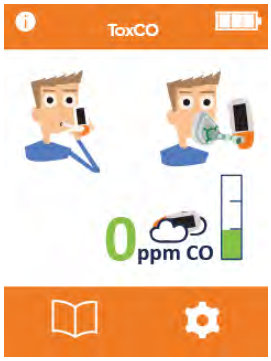
To return to the home screen, press the home icon.



Results save automatically in the breath test log however, there is the option to tag a result with a place, patient's name or ID. To tag a result, press the patient profile icon and enter the place/ID/patient's name. Press the save button.

To switch off, press and hold the power button for 3 seconds. The unit will also power off after 8 hours of inactivity to save power. The display dims after 5 minutes and turns off after 15 minutes.

Ambient monitoring



The ambient air can be tested to check for CO in the environment using the ToxCO®, alerting users to high CO levels in the atmosphere. Once switched on the device will start to sample immediately and the real-time reading will be shown on the home screen at all times, updating every second.

When a CO threshold is breached, the device will log this event and continue to log the live reading every minute. The logging will continue for 8 hours or until the device is switched off. Access the log by pressing the history icon.

CO thresholds

Ambient alarm thresholds are pre-set as per Acute Exposure Guideline Levels (AEGL's)[12]:

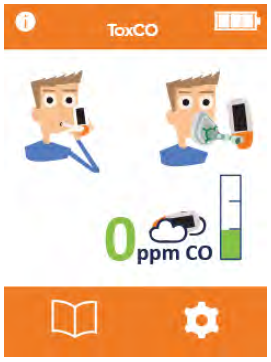
Colour	ppm	Audible alert
Green	<100	No audible alert
Amber	100-199	1 short beep every 2 seconds
Red	≥200	3 short beeps every 3 seconds

Both thresholds can be reduced so that they are triggered at lower levels but cannot be increased to be triggered at higher levels. When an alarm is triggered, the device will automatically start to log in the history each minute for 8 hours or until the device is switched off, so that incidents can be pinpointed to a time and date. Breath test pre-set thresholds are as follows.

Colour	Description	Reading (%COHb & ppm)
Blue	Normal (non-smoker) reading	%COHb ≤0-2.00ppm = 0.9
Red	Abnormal CO level on breath requiring further investigation	%COHb >2ppm = 10+

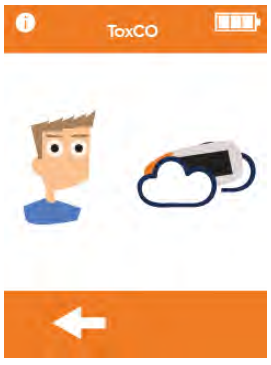
This threshold for colour change can be adjusted up or down to suit local regulations.

Adjusting test thresholds

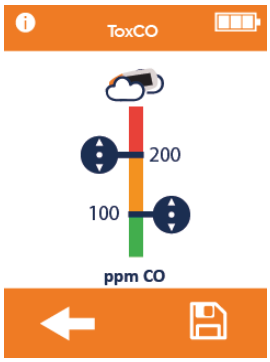


Turn on the device by pressing the power button once. Press the settings icon.

Press the traffic light icon.



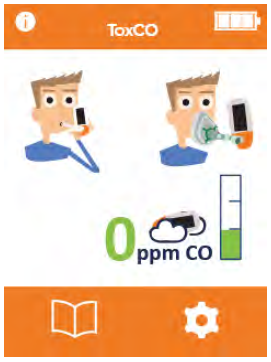
Press the breath test icon or ambient icon depending on which threshold is to be adjusted.



Drag the threshold indicators up or down to the desired concentration; the ppm values for breath testing will adjust automatically with the %COHb.

Pressing the save button will save the changes; pressing the back arrow will abort the changes and return to the previous screen.

Enabling & disabling ppm readings

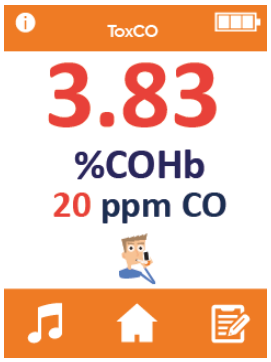


Enabling ppm readings

The ToxCO® is programmed to only show the %COHB when a breath test is taken, however it is possible to also display the reading in ppm.

To enable the ppm display, go to the settings.

Press the crossed out ppm icon.



The breath test will look like this once the ppm readings have been enabled.

Disabling ppm readings

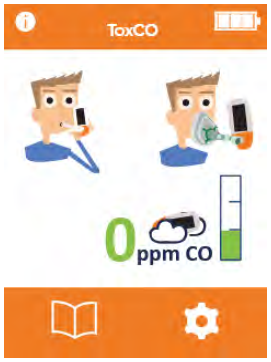
To disable the ppm display, go to the settings.

Press the ppm icon.

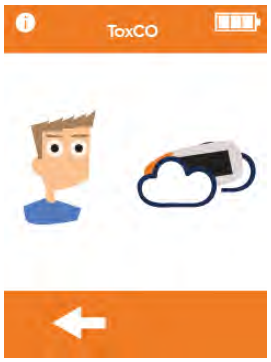
The breath test will look like this once the ppm readings have been disabled.

Reviewing history

The ToxCO® will record/log in its history every breath test but also ambient readings when an alarm threshold is triggered for up to 500 readings for 8 hours or until the device is switched off.

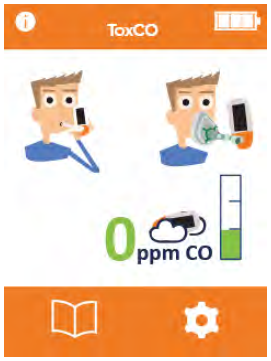


To access the history, press the history icon.



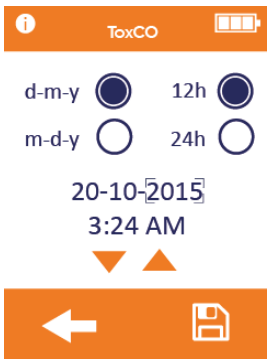
Select either the breath test icon or the ambient icon.

Changing date & time



To change the date & time, press the settings icon.

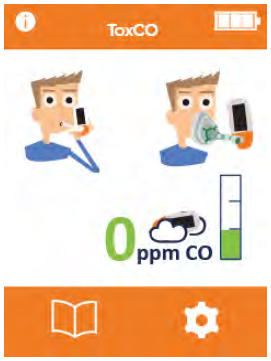
Press the date & time icon.



Select either d-m-y or m-d-y for the date format and 12h or 24h for the time format. With the 12h format, there is also the option to select between am and pm.

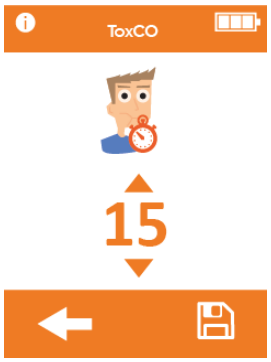
Dates and times are then adjusted by selecting the number to change and pressing the up or down arrows to decrease/increase. Press to save settings or the back arrow to abort changes and return the previous screen.

Changing breath hold time



To change the breath hold time, press the settings icon.

Press the breath-hold time icon.



Changing the breath-hold time is accomplished by pressing the up or down arrow to decrease/increase the time in seconds.

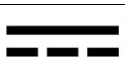
Press the save icon to save setting or the back arrow to abort changes and return to the previous screen.

Technical Specification

Breath Test Concentration range (CO)	0-50%COHb/0-500ppm
Facemask Test Concentration range (CO)	0-28%COHb/0-200ppm
Ambient Test Concentration range (CO)	0-500ppm
Display	Full-colour touchscreen
Detection principle	Electrochemical sensor
Repeatability	≤±5% difference on consecutive readings
Accuracy	≤±3ppm/10% – whichever is greater
Power	3 x AA (LR6 or equivalent) – up to 1000 minutes 1 x CR2032 Lithium coin cell
T_{90} response time	<30 seconds
Operating temperature	0-45°C
Storage/transport temperature	0-50°C
Operating/storage/transport pressure	Atmospheric ±10% (914-1114 mbar)
Operating humidity	15-90% RH non-condensing
Storage/transport humidity	0-95%
Expected sensor operating life	2 years
Sensor sensitivity	1ppm
Sensor drift	<5% per annum
Dimensions	Approx. 37 x 77 x 140 mm
Weight	Approx. 215g (including batteries)
Materials	Case: polycarbonate/ABS blend anti-microbial additive D-piece™: polypropylene SteriBreath™ Eco: paper
H_2 cross interference	≤6%

*Readings of >500ppm at temperatures between 0-14°C can decrease accuracy to ≤±3ppm/15%.

Safety information and device symbols

Degree of protection against electric shock	Type BF applied part
Type of protection against electric shock	Internally powered equipment
Degree of protection against ingress of liquid	IPXO - not protected against water ingress
Degree of safety application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable for use in the presence of flammable mixtures.
Caution	
Direct current	
CE mark	
Type BF applied part	
Dispose of according to WEEE	
Serial number	
Consult electronic instructions for use	
Unique device identification	
Manufacture by and date	
Manufacture date	
Indicator of Medical Device	
Bedfont® logo	

Environment

The ToxCO® complies with the directive EN60601-1-2:2015 4th edition electromagnetic compatibility.

Electromagnetic immunity

The ToxCO® complies with the directive EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding the levels specified in EN55011:2007 Class B.

Guidance and manufacturer's declaration: Electromagnetic immunity			
The ToxCO® is intended for use in the electromagnetic environment specified below. The customer or the user of the ToxCO® should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floor should be wood, concrete or ceramic floor tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-5	–	–	–
Surge IEC61000-4-5	–	–	–
Voltage dips, short interruptions and voltage variations on power supply. IEC 61000-4-11	–	–	–
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location environment.

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10V/m (1kHz 80%) 80MHz-2.7GHz 385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m	10V/m (1kHz 80%) 80MHz-2.7GHz 385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m	Portable and mobile RF communications equipment should be used no closer to the ToxCO® than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol: 

Device and display symbols

Battery condition: full		Exhale		Increase	
Battery condition: low		ppm reading		Decrease	
Battery condition: empty		%COHb reading		Selected	
Breath test		Home		Unselected	
Face mask test		Change D-piece™		Slider (for adjusting up or down)	
Ambient air test		Change CO test thresholds		Red thermometer: temperature too hot to calibrate	
Settings		Save		Blue thermometer: temperature too cold to calibrate	
Create/Edit tag		Change breath hold time		Countdown to sensor change	
Inhale		History		Change sensor	
Hold breath		Next step		Previous step	
Countdown timer		Unit calibrating		Calibration successful	
Calibrate device reminder		Zero failed		Calibration failed	
Calibration overdue		Attach flow meter to gas canister		Ambient CO reading	 
Start calibration		Attach calibration adaptor to D-piece™		Home screen when the sensor change is overdue	
Attach D-piece™ to device and turn on gas flow		Retry calibration		Information	

Warnings and Maintenance

1. If an unexpectedly high reading is displayed, this could indicate CO poisoning. In this case the patient should be referred to the appropriate medical facility for further investigation and treatment.
2. Mouthpieces and face masks should be replaced after every patient.
3. Hands should be washed regularly in accordance with infection control practice.
4. Please do not attempt to modify the equipment in any way or use accessories not specified by the manufacturer. Any attempt to do so will invalidate the warranty and may compromise the safety of the device.
5. Bedfont® will make available upon request service training to appropriately qualified persons.
6. Holding the reset button down for 30 seconds will perform a complete device reset. This will clear any saved data and revert all settings to the factory defaults. After performing a reset, the device will need to have the date/time set and be calibrated before it can be used.
7. Do not use the ToxCO® in an oxygen rich atmosphere.
8. It is recommended that the ToxCO® is calibrated every 6 months, however a calibration MUST be performed within 12 months, using 50ppm CO calibration gas. Please refer to the 'calibration procedure' for more information.
9. The sensor requires replacement every 5 years.
10. Failure to comply with any calibration and sensor replacement requirements will automatically invalidate the unit's warranty.

Cleaning

1. Bedfont® recommends wiping the instrument and D-piece™ external surfaces with a product specifically developed for this purpose. AN EPA registered alcohol free disinfectant should be used, such as Sani-Cloth AF3 Germicidal Disposable Wipe. Cleaning should be performed following the instructions for use specified by the manufacturer of the EPA registered disinfectant. The ToxCO® device should be cleaned for initial use and after each patient use. The D-piece™ cannot be sterilised.

Routine Maintenance

1. Replace the batteries when indicated by the empty symbol.

2. Bedfont® recommends removal of the batteries when the device is not used for prolonged periods of time to prevent leakage.

3. Replace the breath sampling D-piece™ every 30 days or if visibly soiled or contaminated. The ToxCO® will give a reminder during start-up when the D-piece™ should be replaced, see 'change D-piece™' symbol.

4. The sensor should be replaced every 2 years. 60 days prior to the sensor change, a 'countdown to sensor change' symbol will be shown with the date on which the sensor should be changed. This can be ignored by pressing until the date at which the sensor should be changed arrives. At this point, the 'change sensor' symbol will be shown. Change sensor if trained to do so by an approved Bedfont® engineer or send to Bedfont® or your local distributor.

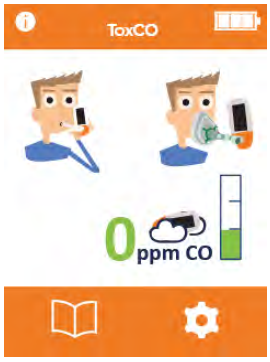
5. Additional technical information can be made available on request; please contact Bedfont® or your local distributor.

6. It is recommended that the ToxCO® is calibrated every 6 months however, a calibration MUST be performed within 12 months, using 50ppm CO calibration gas. Please refer to the 'calibration procedure' for more information.

Calibration

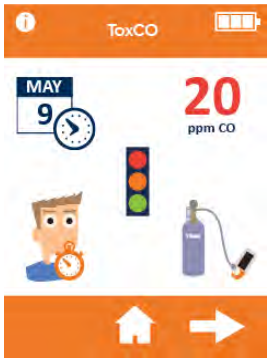
The ToxCO® is calibrated at 21°C (±4°C) before leaving Bedfont®. The ToxCO® must be calibrated within 17-25°C as this is the temperature at which Bedfont® recommend it is to be used.

It is recommended that the ToxCO® is calibrated every 6 months, however a calibration MUST be performed within 12 months, using 50ppm CO calibration gas. Please refer to the 'calibration procedure' for more information.



Turn on the device by pressing the power button once.

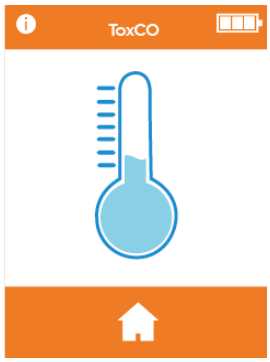
Press the settings icon.



Press the cylinder icon once to proceed.

The device must be zeroed, this will happen automatically.

Do not connect the gas at this stage.



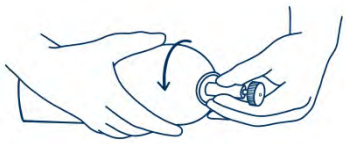
If it is too cold to calibrate (<17°C) a blue thermometer will be shown onscreen.

Move the ToxCO® to a warmer area and try again later.

If it is too hot to calibrate (>25°C) a red thermometer will be shown onscreen.

Move the ToxCO® to a cooler area and try again later.

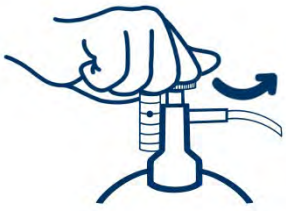
Ensure the fine control valve is in the off position.



Screw the fine control valve and flow indicator assembly to the gas can. This is best done by screwing the gas can into the valve.

Once this has been successfully carried out, the first step of the calibration process will be shown onscreen.

Allow the gas to flow at 1.0 litre per minute.



Allow the gas to flow through the instrument for the duration of the test, again monitoring the rate of flow.

A successful calibration will be indicated by the tick icon, press the home icon to return to the home screen.

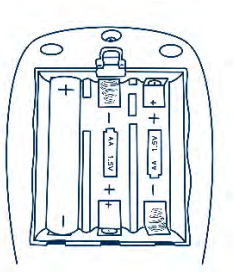
A failed calibration will be indicated by the red cross icon, press the rotating arrow icon to attempt calibration again – if the problem persists see 'troubleshooting' or call the local supplier of Bedfont® products.

Return to the home screen by pressing the home icon.

Troubleshooting

The unit fails to turn on

If the unit fails to turn on, replace the batteries.



Ensure that the batteries are inserted the correct way around, matching the symbols moulded into the plastic.

The sensor has drifted out of specification

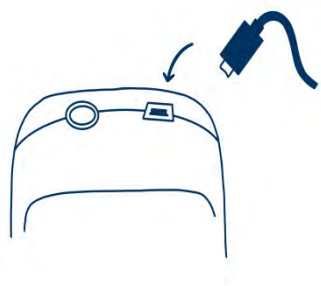
The ToxCO® is calibrated before leaving Bedfont®. However, Bedfont® recommends if the instrument could be reading incorrectly, try the test again with another device, if available, to get a comparison.

Alternatively, check the functionality using Bedfont® check gas or send it back to Bedfont®. The check gas required is Bedfont® 50ppm carbon monoxide in air.

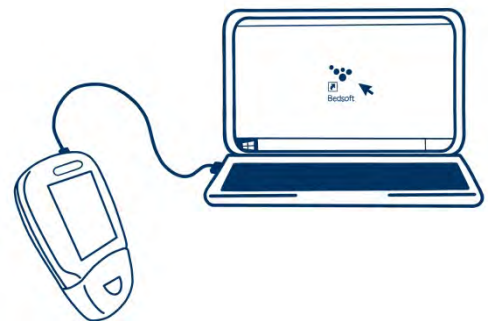
Before beginning, ensure that 'display ppm values' is enabled. Please refer to the 'enabling/disabling ppm reading' section of this manual.

If the final displayed value is less than 45ppm or higher than 55ppm, stop the test and perform a calibration, following the instructions below.

ToxCOdata™ software – connecting to the PC



Place one end of the connection lead into the USB socket on the top of the ToxCO®.



Connect the other end to the USB port on the PC.

Before starting the software, ensure that the ToxCO® is connected to the PC and switched on. Double click the ToxCOdata™ icon on the PC to start the program. Refer to the supplied documentation for how to operate ToxCOdata™. It is recommended that this software is downloaded and installed on a stand-alone computer, not connected to a network, to ensure optimum patient data security. If this software will be installed on a shared network, please ensure that both a domain account and a Bedsoft product account with a secure password has been set up to protect patient data.

Returns procedure

Please contact Bedfont® or its local distributor for instructions on returning goods

Warranty

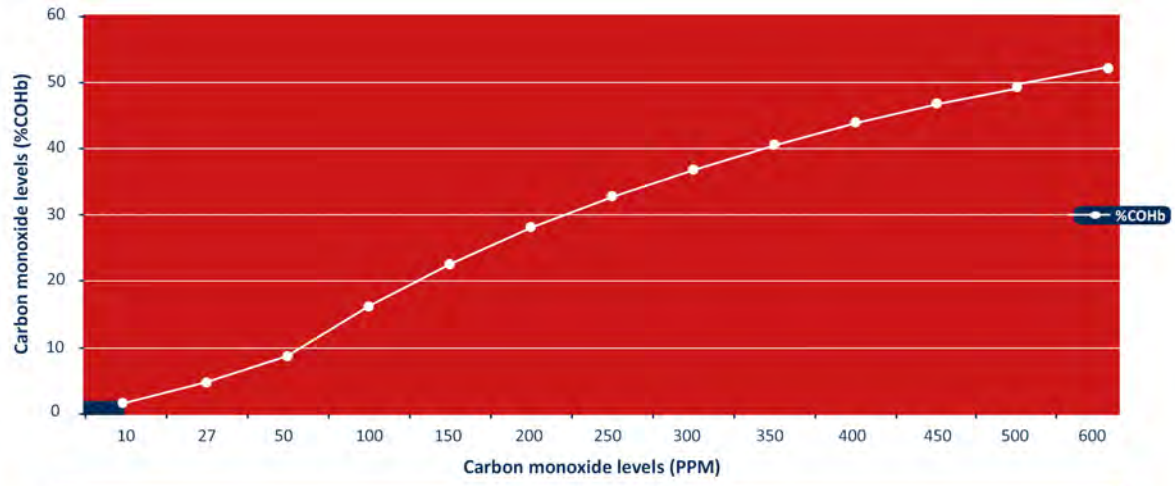
Bedfont® Scientific Limited warrants the ToxCO® (excluding batteries and sensor) to be free of defects in materials and workmanship for a period of 5 years from the date of shipment, subject to service and maintenance requirements. Bedfont's sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned, intact and prepaid, to Bedfont® or the local representative.

These warranties are automatically invalidated if the products are repaired, altered, have had the void labels removed or have been otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.

Never dispose of any electronic instrument or batteries in domestic waste. At the end of the product's life, contact Bedfont® or its distributor for disposal instructions.

Appendix

Breath test/face mask test interpretation chart[10,12]



Key			
Colour	%COhb	Range	Interpretation
●	0-2	Normal	Indicating normal COhb levels
●	2+	Abnormal	Further medical assistance required

Acute Exposure Guideline Levels (AEGL's)[13]

	10 min	30 min	60 min	4 hr	8 hr
AEGL-1	-	-	-	-	-
AEGL-2	420	150	83	33	27
AEGL-3	1700	600	330	150	130

ppm

1. The Level of the chemical in air at or above which the general population could experience notable discomfort.

2. The level of the chemical in air at or above which there may be irreversible or other serious long-lasting effects or impaired ability to escape.

3. The level of chemical in air at or above which the general population could experience life-threatening health effects or death.

IMPORTANT

If there is any doubt, responder should not enter site until it is made safe.

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